APR 2 6 2004

510(k) SUMMARY K022256

Submitted For:	**TUCKER & ASSOCIATES** **198 Ave. de la D'emerald** **Sparks, Nevada 89434-9550**
Submitted by:	JANNA P. TUCKER, President – CEO And Official Correspondent for Tucker & Associates 198 Avenue de la D'emerald Sparks, NV 89434 Phone: 775-342-2612 Fax: 775-342-2613 E-mail: Tuckerjan@aol.com
Date of Submission:	Original: 12 July 2002, "Add to File" revisions and additions 2 April 2004
Classification Name:	Surgical Face Mask, FXX, Class 2 Device
Proprietary Name:	(Multiple Labels)
Common Name:	Face Mask, Surgical
Regulatory Reference:	21 CFR 878.
Predicate Device:	Face Mask, Surgical Mask, K970835
Labels/Labeling:	This device will be marketed to medical device suppliers, Dentist and Doctor Offices, Clinics, Emergency Response Professionals, Hospitals and other healthcare professionals for the Intended Use purposes below.
Intended Use:	This device is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material.
Description:	Non-sterile surgical face mask, white, yellow, pink, blue and green.
Substantial Equivalence:	This device is equivalent to one in commercial distribution approved K970835, but specifically, and most importantly, it has passed all recommended standards and/or tests as follows:

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	Standards and/or tests:
ASTM F2299-03	...materials used in Face Masks
ASTM F1862-00a	...Resistance of Medical Face Masks to Penetration By Synthetic Blood
ASTM F2101-01	...Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials.
MIL M 36945C4.4.1.1.1	Surgical Mask DELTA P, Breathability.
16 CFR 1610.4	Flammability Class – tested at flammability Class 2

Biocompatibility and Agar Diffusion Tests successfully completed.

Performance Characteristics	**Test Method**	**Acceptance Criteria/Results**
Fluid Resistance Performance	ASTM F-1862-00a	No visual detection of penetration.
Filter Efficiency Performance	2.0 Microns	Passed 2.0 Micron Test
Bacterial Filtration Efficiency Performance (%) (BFE)	ASTM F-2101-01	Passed at 97.9%
Differential Pressure (Delta-P)	MIL M 36945C4.4.1.1.1	Passed at 1.8
Flammability Class	16 CFR 1610	Passed at Flammability Class 2

EQUIVALENCY COMPARISONS:

	K970835	**Current Device K022256**
Fluid Resistance	Fluid Resistant	No visual penetration
Filter Efficiency Performance (microns)	2.9 microns	2.0 microns
BFE %	96.4%	97.9%
Delta-P	1.7	1.8
Flammability Class	3	2

Conclusion: **This device is substantially equivalent to the device approved as K970835**

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Tucker & Associates
Ms. Janna Tucker
Official Correspondents
198 Avenue De La D' Emerald
Sparks, Nevada 89434-9550

Re: K022256
Trade/Device Name: Surgical Face Mask Colors: White, Yellow, Pink, Blue and Green
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: April 2, 2004
Received: April 6, 2004

Dear Ms. Tucker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

APPLICANT: **TUCKER AND ASSOCIATES**

510(k) NUMBER: K022256

DEVICE NAME: **SURGICAL FACE MASK**
Colors: White, Yellow, Pink, Blue And Green

This device is intended to be worn to protect both the patient and healthcare personnel From transfer of microorganisms, body fluids and particulate material.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulry

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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